DETAILED ACTION

1. This office action is in response to the amendment filed on June 6, 2011. Claims 15-29 have been cancelled previously. New claims 32 and 33 have been added. Claims 30-33 are currently pending and are under examination.

Pending Rejections

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3. The ionic strength is not identified by units of either Molarity (mol/L) or Molality (mol/g)? What are the units of ionic strength?

Response to Remarks

Applicant's state that it should be made clear that, in the context of the invention, the ionic strength is defined by molality and then state the molality corresponds to 0.15 mol/L in reference to example 7. Applicant's arguments filed June 6, 2011 have been fully considered but they are not persuasive. It is noted that the units provided in the remarks refer to a molarity but state a molality, thus it is further confusing as to whether the ionic strength is molality or molarity. Suggest, placing the units of measure next to the quantity, such as mol/g or mol/l to clarify the ionic strength.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Regarding the method of forming the aqueous albumin solution, it is the position of the examiner that such limitations in the product claim are merely product-by-process limitations. The claims recite that the aqueous albumin solution are formed via a nanofiltration method; however these claims are drawn to a product. Regardless of how the product is made the

components remain the same and as such the process of making the product bears little patentable weight, unless the process produces a materially different product. Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985).

7. Claims 30 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ohmura et al. (EP 0 570 916; previously cited) in view of Lengsfeld et al. (US 2003/0232969 A1) and Winge (U.S. Patent 6,399,357 B1; previously cited).

The rejection was explained in the office action mailed January 6, 2011 and applies equally well to newly presented claim 32.

Response to Remarks

Applicant's state EP 0570916 and U.S. Patent 6,399,357 fails to disclose a virally safe aqueous albumin solution obtained by nanofiltration and in which the transport and binding sites of therapeutically active ingredients are available in the albumin. Applicant's state U.S. 2003/0232969 does not add anything to the prior cited publications to lead one to the presently claimed invention.

Applicant's arguments filed June 6, 2011 have been fully considered but they are not persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on

combinations of references. See ***In re Keller***, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant is also referred to MPEP 2113 Product-by-Process Claims. "[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

Ohmura et al. discloses a process for producing recombinant human serum albumin and a pharmaceutical preparation containing the same. Although, the primary reference suggests the use of an alternative method for purification of albumin, and in view of this, one of ordinary skill in the art would have understood that additional steps to obtain an albumin of sufficient purity; therefore, one of ordinary skill in the art would be motivated to look for a supplementary steps which could assure the intended product to achieve the required purity. The claim is also drawn to a process that comprises steps.

Filtration is routine operation to improve the purity of a protein and moreover ultrafiltration and removal of salts are used in EP 0 570 916. Further, one ordinary skill in the art would be motivated to employ nanofiltration, because Winge discloses the purification albumin using a nanofilter (see particularly claims 14-17 and 35-42). Furthermore, Lengsfeld et al. disclose the removal of virus from protein solutions using a nanofiltration step (see claim 6).

Thus, features of purifications are known or suggested in the art, as seen in the secondary references, and including such features into albumin purification methods of the primary

reference, would have been obvious to one of ordinary skill in the art to obtain the known and recognized functions and advantages thereof for the intended purpose of producing pure albumin.

Therefore, in view of the above, and in view of the combined teachings of the prior art; one of ordinary skill in the art would have been motivated at the time the invention was made to use the already known method of purifying albumin by nanofiltration to eliminate impurities from purified albumin, absent of sufficient objective factual evidence or unexpected results to the contrary.

Claim Objections

1. Claims 32 and 33 are objected to because of the following informalities: the claims are duplicative of claims 30 and 31. The claims are all drawn to virally safe aqueous albumin solutions (i.e. composition claims). Appropriate correction is required or clarification is requested as to how the claims differ.

Conclusion

2. No claims are allowed.

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao can be reached on (571)272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

August 25, 2011
/ANAND U DESAI/
Primary Examiner, Art Unit 1656